

Amended Claims

1. Process for the production of a film-shaped preparation for administration of substances to the human or animal body, said preparation being disintegratable in aqueous media and containing at least one water-soluble polymer and one or more components which produce a gas upon action of moisture or in the presence of an aqueous medium or in the case of a change in temperature, by means of coating a coating compound or two coating compounds on a support, comprising the steps of

- preparing a coating compound which contains the components of the preparation including the gas-forming component(s) by dissolving or suspending the components in a solvent or suspending agent that is substantially free from water;
- spreading this coating compound on a support and drying;

or comprising the steps of

- preparing a first coating compound which contains a first gas-forming component as well as further components of the film-forming preparation by dissolving or suspending said components in an aqueous solvent or suspending agent;
- preparing a second coating compound which contains a first gas-forming component as well as further components of the film-shaped preparation by dissolving or suspending said components in an aqueous solvent or

suspending agent, said first and said second component being reaction partners of a gas-forming reaction;

- spreading the first coating compound on a support and drying, thus forming a first film;
- spreading the second coating compound on a support and drying, thus forming a second film;
- laminating the two films onto each other;

or comprising the steps of:

- preparing a coating compound which contains the components of the preparation including the gas-forming component(s) by dissolving or suspending the said components in a solvent or a suspending agent, with at least one of the gas-forming components being present in microencapsulated form;
- spreading this coating compound on a support and drying.

2. Process according to claim 1, characterized in that the gas-forming component(s) is/are selected from the group comprising carbonates, especially sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, especially sodium hydrogen carbonate, and acids, especially citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid, tartaric acid, as well as acid regulators, especially salts of acetic acid, sodium dihydrogen phosphate or disodium hydrogen phosphate, sodium tartrate, sodium ascorbate.

3. Process according to claim 2, characterized in that as gas-forming components a combination of at least one compo-

ment (a) and at least one component (b) is used, said component(s)

- (a) being selected from the group of the carboxylic acids, preferably from the group comprising citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said components
- (b) being selected from the group comprising sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

4. Process according to any one of the preceding claims, characterized in that the production is accomplished under addition of a pharmaceutical active substance or a combination of two or more pharmaceutical active substances.

5. Process according to any one of the preceding claims, characterized in that the production is accomplished under addition of a flavouring agent, preferably menthol.

6. Film-shaped preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation containing one or more components which produce a gas upon action of moisture or in the presence of an aqueous medium or in the case of a change in temperature, produced in accordance with any one of the preceding claims.

7. Film-shaped preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer,

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said preparation containing one or more components which produce a gas upon action of moisture or in the presence of an aqueous medium or in the case of a change in temperature, characterized in that at least one of the gas-forming components is present in microencapsulated form.

8. Film-shaped preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, said preparation containing one or more components which produce a gas upon action of moisture or in the presence of an aqueous medium or in the case of a change in temperature, characterized in that it has two film layers which are connected with each other, the first film layer containing a first gas-forming component as well as further components of the film-shaped preparation, and the second film layer containing a second gas-forming component as well as further components of the film-shaped preparation, and said first and second gas-forming components being reaction partners of a gas-forming reaction.

9. Preparation according to claim 7 or 8, characterized in that the gas-forming component(s) is/are selected from the group comprising carbonates, especially sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, especially sodium hydrogen carbonate, and acids, especially citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid, tartaric acid, as well as acid regulators, especially salts of acetic acid, sodium dihydrogen phosphate or disodium hydrogen phosphate, sodium tartrate, sodium ascorbate.

10. Preparation according to claim 9, characterized in that as gas-forming components a combination of at least one component (a) and at least one component (b) is used, said component(s)

- (a) being selected from the group of the carboxylic acids, preferably from the group comprising citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and said components
- (b) being selected from the group comprising sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.

11. Preparation according to any one of claims 6 to 10, characterized in that said preparation is capable of producing CO₂ or N₂, preferably under action of water or an aqueous medium or moisture.

12. Preparation according to any one of claims 6 to 11, characterized in that it produces an acid environment in the presence of water.

13. Preparation according to any one of claims 6 to 12, characterized in that said preparation disintegrates in the presence of water or an aqueous medium within 1 s to 5 min, preferably within 1 s to 1 min, especially preferably within 1 s to 30 s.

14. Preparation according to any one of claims 6 to 12, characterized in that said preparation is swellable in aqueous media.

15. Preparation according to any one of claims 6 to 14, characterized in that said preparation contains a pharmaceutical active substance or a combination of two or more pharmaceutical active substances.

16. Preparation according to any one of claims 6 to 15, characterized in that said preparation contains a flavouring agent, preferably menthol.

17. Preparation according to any one claims 6 to 16, characterized in that said preparation comprises at least two layers.

18. Preparation according to any one of claims 6 to 17, characterized in that said preparation has a thickness between 5 μm and 3 mm, preferably between 10 μm and 1 mm, especially preferably between 20 μm and 500 μm .

19. Preparation according to any one of claims 6 to 18, characterized in that it is formulated as an oral, rectal or vaginal administration form for administration of pharmaceutical active agents.